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U.S. Environmental Protection Agency
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PETA
PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Subject: Public Comments on the HPV Challenge Program Test Plan for the Aluminum Stearates Category by Members of the Metal Carboxylates Coalition (Chemtura Corporation, Ferro Corporation and The Shepherd Chemical Company).

The following comments on the HPV Challenge Program test plan for the Aluminum Stearates Category by members of the Metal Carboxylates Coalition (Chemtura Corporation, Ferro Corporation and The Shepherd Chemical Company) are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

In our August 15, 2006 submission, we requested that EPA reopen the comment period for the metal carboxylates test plans, since, as a result of breaking up the category, the numbers of animals to be used has greatly increased and there are a number of serious scientific and animal welfare concerns that need to be addressed. This is the eighth set of comments that we have submitted on the new individual test plans.

The sponsoring companies propose to conduct a 7-day repeat dose toxicity test on aluminum distearate. Since we are unaware of any OECD guidelines for a 7-day repeat dose test, none are specified in the test plan, and no 7-day test is part of the SIDS protocols on which the HPV program is based, we are unable to estimate the number of animals such a test would consume.

This test plan violates the principles of the October 1999 agreement among the EPA, industry, and health, animal protection, and environmental organizations, as well as the December 2000 *Federal Register* notice reconfirming that agreement which directed HPV Challenge Program participants to maximize the use of existing and scientifically adequate data to minimize further testing.

The sponsoring companies note that metal carboxylates readily dissociate into free metal and free acid. The proportion of dissociated salt is dependent on the pH, and the dissociation constant (pKa) is the pH at which 50% dissociation occurs. Although completion of the dissociation study with the two category members, aluminum distearate and aluminum tristearate was not possible due to low water solubility, these compounds are expected to readily dissociate. The dissociation constants for 18 related metal carboxylate compounds tested have pKa values in the range of 5.088 to 8.448. These values indicate that complete dissociation will occur at the physiologically

relevant pH of the mammalian stomach (pH 1.2). The aluminum stearate compounds are expected to behave similarly. The sponsoring companies conclude therefore, that when administered orally, the toxicity of the aluminum stearates is due to the independent action of stearic acid and the free aluminum ion. As a result, mammalian toxicity data for stearic acid and the free aluminum ion, or its simple metal salts, can serve as surrogate data for that of the aluminum stearates.

A 7-day repeat dose toxicity test is proposed for aluminum distearate. Existing data is summarized for repeated dose, reproductive and developmental toxicity endpoints for aluminum chloride. Existing data is summarized for repeated dose toxicity for stearic acid. EPA has already commented on this test plan and notes that "under 40 CFR § 180.910, stearic acid is exempt from the requirement of tolerance (i.e. is designated as 'minimal risk'), obviating the need for further testing under that authority." The theoretical discussion of metal carboxylates dissociation presented in the test plan and summarized above clearly shows, and the sponsoring companies affirm, that data for aluminum chloride and stearic acid can serve as surrogate data for that of aluminum distearate. The only justification offered for proposing this duplicative test is "as a bridging study to show that dissociation product data is representative of the aluminum stearates toxicity." In its comments, EPA rejects this test, noting that "it is not clear how the proposed 7-day repeated-dose bridging study would demonstrate that the dissociation products data are representative of aluminum stearates toxicity". EPA's comments also stress that EPA "does not support further testing for mammalian toxicity endpoints." Further, we are unaware of any OECD guideline for a 7-day repeat dose test and none is specified in the test plan. We strongly object to the proposal of this non-standard, unspecified test.

In summary, we agree with EPA's conclusions that no further testing is necessary. We urge EPA to apply similar reasoning and to reject the 7-day repeat dose toxicity bridging studies that have been proposed in other metal carboxylates test plans.

Sincerely,

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Research & Investigations